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8-21-01

PATENT  
Attorney Docket No. 02386.0046

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of )  
)  
D. HEINEGÅRD et al. )  
)  
Application No. 09/609,383 )  
)  
Filed: July 3, 2000 )  
)  
For: CARTILAGE INTERMEDIATE )  
LAYER PROTEIN AND )  
NUCLEIC ACIDS THEREFOR )

Group Art Unit: 1644

Examiner: P. HUYNH

RECEIVED

AUG 21 2001

Assistant Commissioner for Patents  
Washington, D.C. 20231

TECH CENTER 1600/2900

**RESPONSE TO RESTRICTION REQUIREMENT**

In a Restriction Requirement dated May 17, 2001, the Office required restriction under 35 U.S.C. § 121. The Office set forth thirty-two Groups. Applicants respectfully submit that the Restriction Requirement is improper. However, in order to fulfill the statutory requirement that Applicants respond to the Restriction Requirement, Applicants provisionally elect to prosecute Group I, claims 1-8, drawn to a peptide having a sequence comprising SEQ ID NO:2, *with* traverse. A Petition for Extension of Time and the required fee to extend the shortened statutory period for response to August 17, 2001, is being filed herewith.

Applicants respectfully submit that the Office has improperly limited the scope of the claims through the Restriction Requirement. For example, in issuing the Restriction Requirement, the Office has, without Applicants' permission or approval, limited the scope of claim 1 to that of claim 7. Applicants respectfully submit that they have a statutory right under

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35 U.S.C. § 112, second paragraph, to claim the subject matter they regard as their invention as they choose. Issuing a Restriction Requirement by incorporating an unclaimed limitation in an effort to limit the claim to disclosed embodiments, with the idea that Applicants would have to carve up that claim and pursue the non-elected subject matter in a separate application, violates this right under § 112. Indeed, the C.C.P.A. has characterized such action as tantamount to a refusal to examine. *See In re Weber*, 198 U.S.P.Q. 328 (C.C.P.A. 1978); *In re Haas*, 198 U.S.P.Q. 334 (C.C.P.A. 1978).

In addition, the Restriction Requirement makes it impossible for Applicants to obtain the full scope of their invention, even if every Group were to be pursued in all thirty-two applications that would be required as a result of the Restriction Requirement. That is, even if Applicants pursued each and every Group set forth in the Restriction Requirement, they still would not obtain full coverage for claim 1, which recites, in part, a purified or isolated peptide that is a cartilage intermediate layer protein (CILP). Thus, the Restriction Requirement is improper because it completely eliminates subject matter from the application.

In addition to the outright elimination of claimed subject matter from claim 1, subject matter from claim 9 has been eliminated from this application through the Restriction Requirement. That is, the true scope of claim 9 includes all purified or isolated polynucleotides comprising a sequence encoding a cartilage intermediate layer protein. It is not limited only to those encoded by SEQ ID NO:1. Indeed, the subject matter encompassed by claim 9, and specifically claimed in claim 12, has been completely eliminated from the application by the Restriction Requirement.

Furthermore, the Restriction Requirement incorrectly characterizes many of the claims of this application. For example, the Restriction Requirement states that claims 23 and 35 are drawn to an antibody (see Groups VIII - X). Applicants submit that these claims recite pharmaceutical compositions and kits that comprise CILP protein, analogs, homologs, and fragments. They do not recite antibodies. The Restriction Requirement also asserts that claims 25-27 are drawn to methods of treating using an antibody (Groups XXVI - XXX). Applicants submit that none of these claims are drawn to treating with an antibody.

In addition, Applicants respectfully submit that the non-elected method claims of at least Groups XI - XV should be rejoined with the product claims of Group I once one or more product claims are found to be allowable. In response to *In re Ochiai* and *In re Brouwer*, the Commissioner set forth guidelines for treatment of non-elected process claims. See the Official Gazette, 1184 OG 88 (March 26, 1996). These guidelines have been incorporated into MPEP § 821.04. Under these PTO guidelines, "rejoinder practice" applies to Applicants who have elected claims to a product over claims to a process in compliance with a Restriction Requirement. When it is established that a product claim is allowable, withdrawn process claims that depend from, or otherwise include all the limitations of, the allowable product claim must be rejoined. Applicants respectfully submit that this procedure applies to the present claims.

In view of the above remarks, Applicants request either withdrawal of the Restriction Requirement, at least with respect to Groups I-III, or issuance of a new Restriction Requirement that is in accordance with U.S. law and that correctly characterizes the subject matter of the claims. Furthermore, Applicants request re-joinder of Groups XI - XV upon allowance of the claims of Group I.

In the event that the Office does not withdraw the Restriction Requirement, Applicants reserve the right to prosecute the non-elected claims in divisional or continuation applications.

Early and favorable action on the merits is respectfully requested.

Please grant any extensions of time required to enter this response and charge any required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

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